

This Page Is Inserted by IFW Operations  
and is not a part of the Official Record

## **BEST AVAILABLE IMAGES**

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images may include (but are not limited to):

- BLACK BORDERS
- TEXT CUT OFF AT TOP, BOTTOM OR SIDES
- FADED TEXT
- ILLEGIBLE TEXT
- SKEWED/SLANTED IMAGES
- COLORED PHOTOS
- BLACK OR VERY BLACK AND WHITE DARK PHOTOS
- GRAY SCALE DOCUMENTS

**IMAGES ARE BEST AVAILABLE COPY.**

**As rescanning documents *will not* correct images,  
please do not report the images to the  
Image Problem Mailbox.**

Application No.: 10/066,007  
Amendment Dated: July 19, 2004  
Reply to Office Action of: April 21, 2004

### **REMARKS**

Claims 1-34 and 39 have been cancelled, without prejudice. Accordingly, the claims that are pending and under examination are claims 35-38 (which are part of the Group I claims elected for prosecution based on the Restriction Requirement issued on February 9, 2004) and 40-43 (which depend from claim 35).<sup>2</sup>

We thank the Examiner for the courtesies extended during an Examiner's Interview ("Interview") conducted with the undersigned attorney on June 15, 2004.

During the Interview, we brought to the Examiner's attention, *inter alia*, that the Restriction Requirement issued on February 9, 2004, is inconsistent with the Restriction Requirement issued in U.S. Application Serial No. 09/518,386 ("the parent application"), now U.S. Patent No. 6,365,386 ("the '386 patent), from which the parent case claims benefit as a divisional. See Restriction Requirement dated February 9, 2004, a copy of which is attached hereto as Exhibit B, at pg. 2; and the Notice of Allowability issued in the parent application on September 19, 2001, a copy of which is attached hereto as Exhibit C, at pg. 2. ¶

As shown in the Table below and as we explained to the Examiner during the Interview, claims 35-39, which were originally in Group III in the 9/19/01 Restriction, were moved to Group I in the 2/09/04 Restriction.

---

<sup>2/</sup> In this Response, we are proceeding under the assumption that the Examiner has re-numbered the claims beginning with the second occurrence of claim 3 (*i.e.*, claims 3-38 have been renumbered as 4-39). Although the Examiner does not indicate that she has renumbered the claims, we are making this assumption based on the Examiner's reference to "claim 39" and on the overall content of the Office Action. Accordingly, the Listing of Claims and the Remarks will refer to the re-numbered claims. Should this assumption be incorrect, we respectfully request that the Examiner contact the undersigned attorney at her earliest convenience.

Application No.: 10/066,007  
Amendment Dated: July 19, 2004  
Reply to Office Action of: April 21, 2004

	9/19/01 Restriction	2/9/04 Restriction
Group I	1-14 16-19 29-31 33-39 (claims 35-39 added)	1-14 16-19 29-31 33-34
Group II	15 32 (identical)	15 32
Group III	20-28 (claims 35-39 moved to Group I)	20-28 35-39

During the Interview, the Examiner confirmed the correctness of the 2/09/04 Restriction and recommended that we proceed with prosecution of those claims that have not been previously cancelled and that were elected for prosecution. Accordingly, with a view towards furthering prosecution, we will address the Office Action as it applies to claims 35-39.

Claim 35 has been amended to recite that the polynucleotide is SEQ ID NO: 2, SEQ ID NO: 3, a polynucleotide that encodes the polypeptide of SEQ ID NO: 1, or a polynucleotide that hybridizes to SEQ ID NOs: 2 or 3 under stringent hybridization conditions, wherein the hybridizing polynucleotide encodes a polypeptide having astaxanthin synthase activity. Support for this amendment is found in original claims 36-38, and in the specification at, for example, pg. 6, ln. 27 to pg. 7, ln. 30. See *In re Gardner*, 177 USPQ 396, 397 (CCPA 1973) and MPEP §§608.01(o) and (l).

Application No.: 10/066,007  
Amendment Dated: July 19, 2004  
Reply to Office Action of: April 21, 2004

Claim 35 has further been amended to recite that astaxanthin is recovered from the host cell or the culture medium. Support for this amendment is found in original claim 39, and in the specification at, for example, pg. 8, lns. 14-17.

Claims 36-38 have been amended to conform their dependencies to the renumbering of the claims.

Claims 40-42 have been added. Support for these claims is found in original claims 36-38, and in the specification at, for example, pg. 6, ln. 27 to pg. 7, ln. 30. *See Id.*

Claim 43 has been added. Support for this claim is found in original claims 6-9, and in the specification at, for example, pg. 8, lns. 1-3. *See Id.*

It is submitted that no new matter has been introduced by the foregoing amendments. Approval and entry of the amendments is respectfully solicited.

### **Priority**

The Examiner noted that "[a]n application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification of in an application data sheet." (Office Action at 4).

It is not entirely clear whether the Examiner intended for the aforementioned statement to be regarded as an objection. However, we note that the above-referenced application was previously amended to contain a specific reference to the prior application in the first sentence of the specification as indicated in the transmittal documents filed with this divisional application. *See Request for Filing a*

Application No.: 10/066,007  
Amendment Dated: July 19, 2004  
Reply to Office Action of: April 21, 2004

Rule 1.53(b) Divisional Application, Exhibit A, pg. 2, item 5 ("Amend the specification by inserting before the first line, the sentence: --This application is a divisional of U.S. Application Serial No. 09/518,386 filed March 3, 2000, which is now allowed.--"). Accordingly, the objection is rendered moot and should be withdrawn.

The Examiner further noted that "[u]nfortunately, priority documents were neither found in the parent case nor in the instant case. It is requested that applicant resubmit said priority documents in response to this office action." (*Id.*).

As the Examiner requested, we enclose as Exhibit D a copy of the Submission of Priority Documents Under 35 USC §119 as filed in the parent application on April 18, 2000, including the enclosed priority documents and a copy of the date-stamped postcard evidencing receipt of the priority documents by the PTO.

### **Objection to the Claims**

The Examiner noted the following:

[a]pplicant is advised that should claim 20 be found allowable, claim 38 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. (Office Action at 4).

Initially, we note that claim 20 has been cancelled, without prejudice. Accordingly, it is respectfully submitted that the objection is moot and should be withdrawn.

We note, however, that even if claim 20 had not been cancelled, the Examiner admitted previously that claims 20 and 38 were patentably distinct by placing them in separate groups in the 2/09/04 Restriction Requirement. Thus, even if claim 20

Application No.: 10/066,007  
Amendment Dated: July 19, 2004  
Reply to Office Action of: April 21, 2004

had not been withdrawn, the objection would have been improper. See MPEP §802; 37 CFR §1.142; and Exhibit B at 2-3.

### **§112, Second Paragraph Rejection**

Claims 3-5 were rejected under 35 USC §112, second paragraph. (Office Action at 8). Claims 3-5 have been cancelled, without prejudice. Accordingly, the rejection with regards to these claims is rendered moot and should be withdrawn.

### **§112, First Paragraph, Written Description Rejection**

Claims 1-5, 16, 17, 20, 35 and 39 were rejected under 35 USC §112, first paragraph, as containing "subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention." (*Id.* at 5). In making the rejection, the Examiner asserted, *inter alia*, the following:

...in claims 1-2 applicant is claiming a genus of astaxanthin synthases from all sources and species by mere function. Said claim, as recited, does not allow for recognition of members of the genus from others by structure and is therefore lacking adequate written description. Since said product lacks adequate written description methods of use of said product (claims 20, 35 and 38) also lack sufficient written description. (*Id.* at 6).

Initially, we note that claims 1-5, 16, 17, 20 and 39 have been cancelled, without prejudice. Accordingly, the rejection with regards to these claims is rendered moot and should be withdrawn.

Application No.:	10/066,007
Amendment Dated:	July 19, 2004
Reply to Office Action of:	April 21, 2004

With a view towards furthering prosecution, claim 35 has been amended to recite specific polynucleotide sequences, as well as the specific activities of the polypeptides encoded by the hybridizing polynucleotide sequences (astaxanthin synthetase activity). It is respectfully submitted that claim 35, as amended, is clearly tied to a structure (*i.e.*, SEQ ID NOs: 1, 2 and 3) and that this structure correlates with the recited activity. Accordingly, the rejection of claim 35 is rendered moot and should be withdrawn.

#### **§101 Rejection**

Claims 4-5, 7-9, 11-14, 17-19, 29-31 and 36-38 were rejected under 35 USC §101 as claiming the same invention as that of claims 3-4, 6-8, 10-13, 15-20 and 35-37 of the '386 patent. (*Id.* at 2).

Initially, we note that claims 4-5, 7-9, 11-14, 17-19 and 29-31 have been cancelled, without prejudice. Accordingly, the rejection with regards to these claims is rendered moot and should be withdrawn.

As to claims 36-38, we note that it is well settled that a rejection under §101 requires that the claims of the cited reference and the rejected claims define "identical subject matter." *In re Vogel*, 164 USPQ 619, 621 (CCPA 1970). In other words, the scope of the claims must be **identical** for the "same invention" to be found.

With a view towards furthering prosecution, claim 35, from which claims 36-38 depend, has been amended to recite that astaxanthin is recovered from the host cell or the culture medium and to include polynucleotide sequences that hybridize under stringent conditions to the complement of SEQ ID NOs: 2 and 3. The claims of the '386

Application No.:	10/066,007
Amendment Dated:	July 19, 2004
Reply to Office Action of:	April 21, 2004

patent do not recite these limitations. Thus, the '386 claims cited by the Examiner and claims 36-38, as amended, are "not identical." Accordingly, it is respectfully submitted that the rejection is rendered moot and should be withdrawn.

### **Obviousness-type Double Patenting**

Claims 1-3, 6, 10, 16, 21, 33-35 and 39 were rejected under the judicially created doctrine of obviousness-type double patenting over claims 1-2, 5, 9 and 14 of the '386 patent. (Office Action at 3). In making the rejection, the Examiner asserted that "the subject matter claimed in the instant application is fully disclosed in the patent and is covered by the patent since the patent and the application are claiming common subject matter." (*Id.*). Further, the Examiner contended that "there is no apparent reason why applicant was prevented from presenting claims corresponding to those of the instant application during prosecution of the application which matured into a patent." (*Id.*).

Initially, we note that claims 1-3, 6, 10, 16, 21, 33, 34 and 39 have been cancelled, without prejudice. Accordingly, the rejection with regards to these claims is rendered moot and should be withdrawn.

With respect to claim 35, we respectfully traverse the rejection for the reasons set forth below.

As noted above, the present application is related to the '386 patent as a divisional application. The claims filed in the application underlying the '386 patent were subject to a three way restriction requirement. The claims as issued in the '386 patent were directed to Group I. We note that in the Notice of Allowance, the Examiner



Application No.: 10/066,007  
Amendment Dated: July 19, 2004  
Reply to Office Action of: April 21, 2004


expressly cancelled claims 35-39 as directed to a "non-elected invention." See Exhibit C at 2. Claims 35-39 were placed into Group III. *Id.*

In view of this procedural history, we note that 35 USC §121 prohibits the use of the '386 patent as a reference against this divisional application.<sup>3</sup> Accordingly, it is respectfully submitted that the rejection is in error and should be withdrawn.

For the reasons set forth above, entry of the amendments, withdrawal of the objections and rejections, and allowance of the claims are respectfully requested. If the Examiner has any questions regarding this paper, please contact the undersigned attorney.

Respectfully submitted,

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Mail Stop Amendment, Commissioner for Patents, P.O. Box. 1450 Alexandria, VA 22313-1450, on July 19, 2004.



Gonzalo Merino, Ph.D., Reg. No. 51,192

By: 

Gonzalo Merino, Ph.D.  
Reg. No. 51,192  
BRYAN CAVE LLP  
1290 Avenue of the Americas  
New York, NY 10104-3300  
Phone: (212) 541-2000  
Fax: (212) 541-4630

<sup>3/</sup>

We also note that notwithstanding the Examiner's current arrangement of claims in the 2/09/04 Restriction Requirement, the 9/19/01 Restriction Requirement cannot be rewritten or withdrawn. To do so would impermissibly allow the PTO to "rewrite history." Thus, because we have elected to prosecute in this application claims that were unambiguously restricted out of the application (*i.e.*, claims 35-38) that issued as the '386 patent, §121 prohibits the Examiner from using the '386 patent against the present application.



UNITED STATES PATENT AND TRADEMARK OFFICE

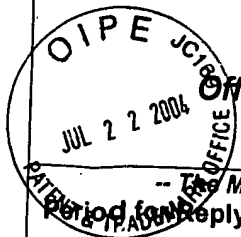
UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO. 10/066,007	FILING DATE JUL 22 2004 02/09/2004	FIRST NAMED INVENTOR Tatsuo Hoshino	ATTORNEY DOCKET NO. 20350 US1 (C38435/128572)	CONFIRMATION NO. 3899
BRYAN CAVE 1290 AVENUE OF THE AMERICAS 33RD FLOOR NEW YORK, NY 10104			EXAMINER MONSHIPOURI, MARYAM	
			ART UNIT 1652	PAPER NUMBER

DATE MAILED: 02/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

C38435/128572  
KOH/XIY/mem  
FEB 12  
Docketed - 44



# Office Action Summary

Application No.	Applicant(s)	
10/066,007	HOSHINO ET AL.	
Examiner	Art Unit	
Maryam Monshipouri	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 01 January 1939.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☐ Claim(s) \_\_\_\_\_ is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-39 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |



Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-14, 16-19, 29-31 and 33-39, drawn to DNA sequences encoding astaxanthin synthases from *P. rhodozyma*, vectors and host cells comprising said sequences, classified in class 435, subclass 183.
- II. Claims 15 and 32 are directed to said synthases, classified in class 435, subclass 183.
- III. Claims 20-28 drawn to precosses for producing astaxanthin, classified in class 435 subclass 67.

The inventions are distinct, each from the other because of the following reasons:

The DNA of Group I is patentably distinct from the polypeptide of Group II because each product has an independent chemical structure and function.

Inventions II and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the Astaxanthin of Group III may br prepared by synthetic methods which are entirely different than the method of Group III. The DNA of Group I is unrelated to the method of Group III because said product is neither made nor used by said method.

The processes of Groups III and IV are patentably distinct because each method has different steps and different end-points.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter as shown by their separate classification, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provision of MPEP section 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all the criteria for patentability including the requirement of 35 U.S.C. 101, 102, 103 and 112. Until an asserted product claim is found allowable, an otherwise proper restriction requirement between product claims

Art Unit: 1652

and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. section 103(b)," 1184 O.G. 86(March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include limitations of the product claim. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP section 804.01.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Maryam Monshipouri, Ph.D. whose telephone number is (571) 272-0932.

The examiner can normally be reached between 8:00 a.m. and 4:30 p.m. daily except for alternate Mondays.

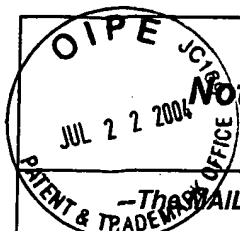
Art Unit: 1652

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Dr. P. Achutamurthy, can be reached at (571) 272-0928. The OFFICIAL fax number for Technology Center 1600 is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

~~M. Monshipouri~~  
Maryam Monshipouri, Ph.D.

Primary Examiner



## Notice of Allowability

Application No.

09/518,386

Applicant(s)

Hoshino et al.

Examiner

Maryam Monshipouri

Art Unit

1652



—The MAILING DATE of this communication appears on the cover sheet with the correspondence address—

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance and Issue Fee Due or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☐ This communication is responsive to \_\_\_\_\_
2. ☒ The allowed claim(s) is/are 1, 3-14, 16-19, 29-31, 33, and 34
3. ☒ The drawings filed on Mar 3, 2000 are acceptable as formal drawings.
4. ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☒ All    b) ☐ Some\*    c) ☐ None of the:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

5. ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application. **THIS THREE-MONTH PERIOD IS NOT EXTENDABLE FOR SUBMITTING NEW FORMAL DRAWINGS, OR A SUBSTITUTE OATH OR DECLARATION.** ~~This three-month period for complying with the REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL is extendable under 37 CFR 1.150(a).~~

6. ☐ Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient. A SUBSTITUTE OATH OR DECLARATION IS REQUIRED.
7. ☐ Applicant MUST submit NEW FORMAL DRAWINGS
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No. \_\_\_\_\_
- (b) ☐ including changes required by the proposed drawing correction filed \_\_\_\_\_, which has been approved by the examiner.
- (c) ☐ including changes required by the attached Examiner's Amendment/Comment or in the Office action of Paper No. \_\_\_\_\_

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings. The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftsperson.

8. ☐ Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Any reply to this letter should include, in the upper right hand corner, the APPLICATION NUMBER (SERIES CODE/SERIAL NUMBER). If applicant has received a Notice of Allowance and Issue Fee Due, the ISSUE BATCH NUMBER and DATE of the NOTICE OF ALLOWANCE should also be included.

### Attachment(s)

- 1 ☐ Notice of References Cited (PTO-892)
- 2 ☐ Notice of Informal Patent Application (PTO-152)
- 3 ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 4 ☒ Interview Summary (PTO-413), Paper No. 12
- 5 ☒ Information Disclosure Statement(s) (PTO-1449), Paper No(s). 3&5
- 6 ☒ Examiner's Amendment/Comment
- 7 ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
- 8 ☒ Examiner's Statement of Reasons for Allowance
- 9 ☐ Other





Application/Control Number: 09/518,386

Page 2

Unit: 1652

An **Examiner's Amendment** to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

Authorization for this Examiner's Amendment was given in a telephone interview with Mr. Kevin C. Hooper, on 9/14/01.

It should be noted that restriction of the claims as previously indicated is not correct due to an inadvertent error of the examiner. The original pending claims should be grouped as indicated below:

**Group I**, claims 1-14, 16-19, 29-31 and 33-34, drawn to DNA sequences encoding astaxanthin synthase from *P. rhodozyma*, vectors and host cells comprising said sequences and methods of expressing said sequences, classified in class 435, subclass 183.

**Group II**, claims 15 and 32, drawn to said synthase, classified in class 435, subclass 183.

**Group III**, claims 20-28 and 35-39, drawn to processes of use of said synthase, classified in class 435, subclass 67.

The inventions are distinct each from the other for the reasons indicated in Paper # 8.

Applicant elected Group I invention without traverse.

#### **Examiner's Amendment to the Claims**

**Claims 35-39 directed to non-elected invention are canceled.**

In claim 6 , line 1, after enzyme, insert --- derived from *P. rhodozyma* ---.

Art Unit: 1652

In claim 6, line 2, after "activity", insert which catalyzes the reaction of beta-carotene to astaxanthine ---.

In claim 10, line 2, after "enzyme", insert --- derived from *P. rhodozyma* ---.

In claim 14, line 3, after "SEQ ID No:2; ", delete "and/".

In claim 16, line 1, after "polypeptide", insert --- derived from *P. rhodozyma* ---.

#### **Examiner's Amendments to the Specification**

The following is an **Examiner's Statement of Reasons for Allowance**:

Claims 1, 3-14, 16-19, 29-31, 33-34 are directed to isolated polynucleotides derived from *P. rhodozyma* encoding an astaxanthin synthase of specific amino acid sequence, vectors and host cells comprising said polynucleotides and methods of expressing said polynucleotides. Claimed polynucleotide sequences are free of prior art. Further, the prior art does not teach or suggest preparing such specifically claimed polynucleotides. Hence, the claimed polynucleotides are also non-obvious. Since claimed polynucleotides are both novel and non-obvious, vectors and host cells comprising said polynucleotides, and methods of expressing said polynucleotides are also novel and non-obvious.

**Claims 1, 3-14, 16-19, 29-31 and 33-34 are allowed.**

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue

Art Unit: 1652


fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Maryam Monshipouri, Ph.D. whose telephone number is (703) 308-1083. The Examiner can normally be reached daily from 8:30 A.M. to 4:30 P.M.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Dr. P. Achutamurthy, can be reached at (703) 308-3804. The OFFICIAL fax number for Technology Center 1600 is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Maryam Monshipouri Ph.D.  
Patent Examiner

  
REBECCA E. PROUTY  
PRIMARY EXAMINER  
GROUP-1800  
1600



UNITED STATES DEPARTMENT OF COMMERCE  
Patent and Trademark Office

NOTICE OF ALLOWANCE AND ISSUE FEE DUE

HM12/0919

MARK E WADDELL ESG  
BRYAN CAVE LLP  
245 PARK AVENUE  
NEW YORK NY 10167-0034

APPLICATION NO.	FILING DATE	TOTAL CLAIMS	EXAMINER AND GROUP ART UNIT	DATE MAILED
09/518,386	03/03/00	022	MONSHIPOURI, M	1652 09/19/01
First Named Applicant	HOSHINO,	35 USC 154(b) term ext. = 0 Days.		

TITLE OF INVENTION ASTAXANTHIN SYNTHASE

ATTY'S DOCKET NO.	CLASS-SUBCLASS	BATCH NO.	APPLN. TYPE	SMALL ENTITY	FEE DUE	DATE DUE
1 20350/111657	435-183.000	M15	UTILITY	NO	\$1240.00	12/19/01

**THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED.**

**THE ISSUE FEE MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED.**

**HOW TO RESPOND TO THIS NOTICE:**

I. Review the SMALL ENTITY status shown above.  
If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

- A. If the status is changed, pay twice the amount of the FEE DUE shown above and notify the Patent and Trademark Office of the change in status, or
- B. If the status is the same, pay the FEE DUE shown above.

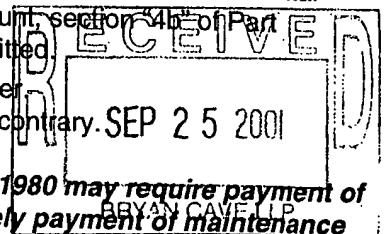
If the SMALL ENTITY is shown as NO:

- A. Pay FEE DUE shown above, or
- B. File verified statement of Small Entity Status before, or with, payment of 1/2 the FEE DUE shown above.

II. Part B-Issue Fee Transmittal should be completed and returned to the Patent and Trademark Office (PTO) with your ISSUE FEE. Even if the ISSUE FEE has already been paid by charge to deposit account, Part B Issue Fee Transmittal should be completed and returned. If you are charging the ISSUE FEE to your deposit account, section 34b of Part B-Issue Fee Transmittal should be completed and an extra copy of the form should be submitted.

III. All communications regarding this application must give application number and batch number. Please direct all communications prior to issuance to Box 15000, P.O. Box 15000, Alexandria, VA 22304-5000.

**IMPORTANT REMINDER: Utility patents issued on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.**



YOUR COPY



April 18, 2000

Docket No. 20350/111657

In re Patent Application of:  
Tatsuo HOSHINO, et al.

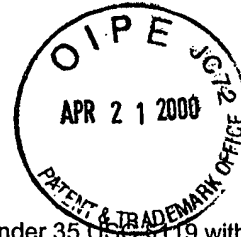
Serial No.: 09/518,386

Filed: March 3, 2000

For: **ASTAXANTHIN SYNTHASE**

Enclosed:

1. Submission of Priority Documents Under 35 USC § 119 with Certificate of Mailing (1.p)
2. Two (2) Certified Priority Documents EP 99104668.1 and EP00101666.6
3. Two (2) Assignments and Recordation Form Cover Sheets (4 pp)
4. Two (2) Checks for \$40.00 each (Assignment fees)
5. Return Postcard



**PLEASE DATE STAMP AND RETURN TO ACKNOWLEDGE RECEIPT**

KCH:sc

**DOCKETED**

DATE 4-27-2000

INITIAL MM

# PATENTS ONLY

Tab settings → → → ▼ ▼ ▼ ▼ ▼ ▼ ▼ ▼

To the Honorable Commissioner of Patents and Trademarks: Please record the attached original documents or copy thereof.

1. Name of conveying party(ies):

**F. HOFFMANN-LA ROCHE AG**

Additional names(s) of conveying party(ies)

☐ Yes ☒ No

3. Nature of conveyance:

☒ Assignment

☐ Merger

☐ Security Agreement

☐ Change of Name

☐ Other

Execution Date: **April 10, 2000**

2. Name and address of receiving party(ies):

Name: **ROCHE VITAMINS INC.**

Address: **43 Water view Blvd.**

City: **Parsippany**

State/Prov.: **NJ**

Country: **USA**

ZIP: **07054-1219**

Additional name(s) & address(es)

☐ Yes ☒ No

4. Application number(s) or registration numbers(s):

If this document is being filed together with a new application, the execution date of the application is:

Patent Application No.

Filing date

B. Patent No.(s)

**09/518,386**

**March 3, 2000**

Additional numbers

☐ Yes ☒ No

5. Name and address of party to whom correspondence concerning document should be mailed:

Name: **Mark E. Waddell**

Registration No. **31,803**

Address: **BRYAN CAVE LLP**

**245 Park Avenue**

City: **New York**

State/Prov.: **NY**

Country: **USA**

ZIP: **10167-0034**

6. Total number of applications and patents involved:

**1**

7. Total fee (37 CFR 3.41):.....\$ **40.00**

☒ Enclosed - Any excess or insufficiency should be credited or debited to deposit account

☐ Authorized to be charged to deposit account

8. Deposit account number:

**02-4467**

DO NOT USE THIS SPACE

9. Statement and signature.

To the best of my knowledge and belief, the foregoing information is true and correct and any attached copy is a true copy of the original document.

**Kevin C. Hooper**

Name of Person Signing

Signature

Date

Total number of pages including cover sheet, attachments, and

**2**

# Assignment

We,

F. Hoffmann-La Roche AG (Assignor), a Swiss Company  
of 124 Grenzacherstrasse, CH-4070 Basle (Switzerland)

hereby assign to

**ROCHE VITAMINS INC. (Assignee)**

a corporation organized and existing under and by virtue of the laws of the State of Delaware,  
and having its principal place of business at 43 Waterview Blvd., Parsippany, New Jersey,  
U.S.A.,

all of our right, title and interest within the United States of America and its territorial  
possessions in and to the invention described and claimed in a patent application entitled

## **ASTAXANTHIN SYNTHASE**

which is about to be filed in the U.S. Patent Office in the name(s) of the inventor(s)

**Tatsuo Hoshino, Kazuyuki Ojima, Yutaka Setoguchi**

and in respect of which a declaration and Power of Attorney was executed on:

**February 25 and 28, 2000**

and in and to said patent application and Letters Patent that may issue thereon.

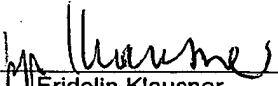
Said U.S. Patent Application is based upon the following foreign application(s):

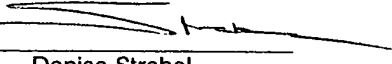
**in Europe on March 9, 1999 under No. 99104668.1 and  
February 1, 2000 under No. 00101666.6**

and was assigned to F. Hoffmann-La Roche AG, Basle, Switzerland, by the said inventor(s) by  
an assignment dated February 25 and 28, 2000.

Basle, Switzerland, this 10th day of April 2000.

**F. Hoffmann-La Roche AG**

  
Fridolin Klausner  
Holder of procuration

  
Denise Strebel  
Mandatory

PATENTS ONLY

Tab settings → → → ▼ ▼ ▼ ▼ ▼

To the Honorable Commissioner of Patents and Trademarks: Please record the attached original documents or copy thereof.

1. Name of conveying party(ies):

Tatsuo HOSHINO  
Kazuyuki OJIMA  
Yutaka SETOGUCHI

Additional names(s) of conveying party(ies) ☐ Yes ☒ No

3. Nature of conveyance:

- ☒ Assignment ☐ Merger  
☐ Security Agreement ☐ Change of Name  
☐ Other \_\_\_\_\_

Execution Date: February 25, 2000 and February 28, 2000

2. Name and address of receiving party(ies):

Name: F. HOFFMANN-LA ROCHE AG

Address: 124 Grenzacherstrasse

City: CH-4070 Basle State/Prov.: \_\_\_\_\_

Country: SWITZERLAND ZIP: \_\_\_\_\_

Additional name(s) & address(es) ☐ Yes ☒ No

4. Application number(s) or registration numbers(s):

If this document is being filed together with a new application, the execution date of the application is: \_\_\_\_\_

Patent Application No. Filing date  
09/518,386 March 3, 2000

B. Patent No.(s) \_\_\_\_\_

Additional numbers ☐ Yes ☒ No

5. Name and address of party to whom correspondence concerning document should be mailed:

Name: Mark E. Waddell

Registration No. 31,803

Address: BRYAN CAVE LLP

245 Park Avenue

City: New York State/Prov.: NY

Country: USA ZIP: 10167-0034

6. Total number of applications and patents involved: 1

7. Total fee (37 CFR 3.41):.....\$ 40.00

☒ Enclosed - Any excess or insufficiency should be credited or debited to deposit account

☐ Authorized to be charged to deposit account

8. Deposit account number:

02-4467

DO NOT USE THIS SPACE

9. Statement and signature.

To the best of my knowledge and belief, the foregoing information is true and correct and any attached copy is a true copy of the original document.

Kevin C. Hooper

Name of Person Signing

[Signature]  
Signature

April 18, 2000  
Date

Total number of pages including cover sheet, attachments, and



## Assignment

WHEREAS, I/WE

**Tatsuo Hoshino, Kazuyuki Ojima, Yutaka Setoguchi**

the ASSIGNOR(S), have invented certain new and useful improvements in

### **ASTAXANTHIN SYNTHASE**

which are described and claimed in application for United States Letters Patent in respect of which a Declaration and Power of Attorney was executed on

*February 25 and 26, 2000*

which application is based upon the following foreign application(s)

**In Europe on March 9, 1999 under No. 99104668.1 and**

**February 1, 2000 under No. 00101666.6**

NOW, THEREFOR, for and in consideration of the sum of One Dollar (\$1.00) and other good and valuable considerations to me (us) in hand paid, the receipt and sufficiency whereof are hereby acknowledged, I/we have sold, assigned and set over, and by these presents do hereby sell, assign and set over unto

**F. Hoffmann-La Roche AG, a Swiss Company  
of 124 Grenzacherstrasse, CH-4070 Basle (Switzerland) the Assignee**

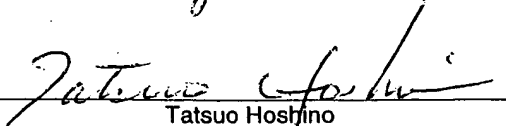
and the said Assignee's legal representatives, successors and assigns, the entire right, title and interest, in and to the said invention within the United States of America and its territories and possessions, and in and to said application and the Letters Patent of the United States of America that may be granted therefor, together with the right to extend the protection thereof to the various territories and possessions now owned or which may be acquired hereafter by the United States of America; and I/we do hereby request and authorize the Commissioner of Patents to issue said Letters Patent to the above-mentioned Assignee agreeably with the terms of this assignment.

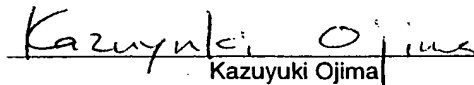
UPON SAID CONSIDERATION, I/we do hereby covenant and agree with the said Assignee that I/we will not execute any writing or do any act whatsoever conflicting with these presents, and that I/we will at any time upon request without further or additional consideration, but at the expense of the said Assignee, execute such additional assignments and other writings and do such additional acts as said Assignee may deem necessary or desirable to perfect the Assignee's enjoyment of this grant, and render all necessary assistance in making application for and obtaining original, divisional, reissued, or extended Letters Patent of the United States of America on said invention, and in enforcing any rights or choses in action accruing as a result of such applications or patents, including but not limited to, giving testimony in any proceedings or transactions involving such applications or patents, and executing preliminary statements and other affidavits, it being understood that the foregoing covenant and agreement shall bind and inure to the benefit of the assigns and legal representatives of all parties hereto.

IN WITNESS WHEREOF, this Assignment has been executed by the Assignor(s)

at *Kamakura*

on *February 25, 2000 and February 26, 2000*

  
Tatsuo Hoshino

  
Kazuyuki Ojima

  
Yutaka Setoguchi

**BRYAN CAVE LLP**  
245 Park Avenue  
New York, NY 10167-0034  
(212) 692-1800

1st Bank of New York  
New York, NY 10022  
1-1/210

Check Number  
**25108**

April 18, 2000

Forty & 0/100

Net Amount  
\$40.00

TO THE  
ORDER OF

Commissioner of Patents and  
Trademarks

09/518,386

SIGNATURE HAS A COLORED BACKGROUND • BORDER CONTAINS MICROPRINTING

⑈0000025108⑈ ⑆021000018⑆6302197634⑈

Check NO. 25108

Inv.Date	BC Ref#	Invoice #	Description	Amount Paid
04/18/00	513431	KCH-111657	Recording assignment fee #1 SN 09/518,386 (Ref.	40.00

CHECK TOTAL 40.00

BRYAN CAVE LLP

245 Park Avenue

New York, NY 10167-0034

(212) 692-1800